# **EXHIBIT A**

# DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP

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July 14, 2004

Sean R. Matt, Esq. Hagens Berman, LLP 1301 Fifth Avenue, Suite 2900 Seattle, WA 98101

Re:

Baxter Healthcare Corporation De Minimus Drugs

Dear Sean:

The said

Pursuant to my May 10, 2004 letter, the information set forth below and in the accompanying materials demonstrates that plaintiffs should not pursue certain drugs manufactured or produced by Baxter Healthcare Corporation ("Baxter") in the AWP MDL litigation. The drugs addressed below should not be pursued because (1) they are administered predominately in inpatient settings where reimbursement is not based on AWP; (2) the sales to entities that would administer these drugs in an outpatient setting are relatively small; (3) certain drugs simply were not sold at all or only until recently by Baxter; and/or the so-called "spreads" are minimal. Accordingly, Baxter requests that plaintiffs agree to strike these drugs from Appendix A to the Amended Master Consolidated Complaint ("AMCC").

# I. The Agreement On Limited Discovery

After the parties' meet and confer on April 26, 2004, plaintiffs agreed to accept Baxter's production of limited data regarding drugs that are administered predominantly in inpatient settings. See Letter from S. Matt to M. DeLancey, dated 4/27/04 (sent via electronic mail). As a condition to the limited production, plaintiffs requested that Baxter produce data showing (i) total annual sales, broken down by distribution channel; and (ii) all Wholesale Acquisition Costs ("WACs") and Average Sales Prices ("ASPs") available. Plaintiffs also reserved the right to pursue relevant documents for any drug listed as *de minimus*.

On May 10, 2004, Baxter accepted plaintiffs' conditions and proposed that the production of data be limited to the years 1997 through 1999. <u>See</u> Letter from M. DeLancey to S. Matt, dated 5/12/04.

On May 26, 2004, plaintiffs accepted Baxter's proposed time limitation. To the extent Baxter did not sell certain drugs during the agreed upon period, plaintiffs requested that Baxter provide data for another sample period. <u>See</u> Letter from S. Matt to M. DeLancey, dated 5/26/04.

## II. Overview of the Data

The Baxter drugs identified in Appendix A to the AMCC are manufactured by one of three Baxter divisions: Medication Delivery, Anesthesia & Critical Care, or BioScience. Each division has different computer systems and capability to gather and track data – all of which may vary from year to year. Nonetheless, for purposes of this letter, we have collected and/or calculated from each division available data on sales, WACs and ASPs for the years 1997 through 1999. Where Baxter did not sell the applicable drug during that period, Baxter collected data from 2000 through 2002.<sup>1</sup>

All of the Baxter drugs at issue are administered by injection, not orally. Thus, they are not sold through retail pharmacies or to Pharmacy Benefit Managers ("PBMs"), and are not listed on PBM formularies.

# A. Average Sales Prices

Baxter calculated ASPs by dividing the total sales of a drug by the total of number of units sold during the relevant three-year period. With respect to Medication Delivery, the calculation of ASPs included rebates, administrative fees, and cash discounts. Medication Delivery paid rebates to high utilization customers who, as shown below, generally were customers in the inpatient setting. Also, Medication Delivery included administrative fees in the ASP calculations, even though those fees generally are paid to Group Purchasing Organizations ("GPOs"), representing hospitals. Because these fees are paid to the GPO and not to the actual customer, they are not considered discounts in the price paid by customers. Moreover, since the GPO's members are hospitals, even if the administrative fee is considered a discount, such

<sup>&</sup>lt;sup>1</sup> Baxter's production of data through the end of 2002 is without prejudice to its claim that the relevant time period in this action does not extend beyond September 6, 2002, the date plaintiffs filed the Master Consolidated Complaint.

transactions would be with providers in the inpatient settings where reimbursement is not based on AWP, and thus are irrelevant to the AWP MDL.<sup>2</sup>

For Anesthesia & Critical Care, the ASP calculations reflect average contract pricing and do not include rebates, cash discounts or administrative fees. Similarly, BioScience did not include rebates in its calculations of ASPs because no rebates were paid on any of its drugs listed below. BioScience also did not include administrative fees because they too are paid to GPOs and do not affect pricing to the end user. Although BioScience does not offer cash discounts to many of its customers, when it did, the cash discount BioScience offered during the relevant time period was 1%, which is not reflected in its ASP calculations.

## B. Wholesale Acquisition Costs

To provide a conservative view of fluctuations in WAC pricing during a given year, the WAC data reported below and in the attachments represents the maximum WAC reported annually for each of the NDCs. This is true even when the WAC prices changed (i.e., increased) during the later part of a year. As a result, the so-called "spread" between ASPs and WACs could be significantly lower than the "spread" reported below and in the attachments.

To the extent WAC data was unavailable, Baxter has provided historical AWPs, where available, or 2003 AWPs.<sup>3</sup> Such data is unavailable for a variety of reasons. For example, WAC pricing for the BioScience drugs addressed in this letter are not available because those drugs were not sold to wholesalers. Similarly, WACs were not available for some of the Medication Delivery drugs because they were sold directly to providers; not through wholesalers. In those instances, we used AWPs to calculate the so-called "spread." In addition, where applicable, Medication Delivery calculated WACs based on actual sales transactions with wholesalers and dealers.<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> The program used by Medication Delivery to gather and retrieve ASP data did not easily permit the exclusion of administrative fees.

<sup>&</sup>lt;sup>3</sup> The AWPs for Medication Delivery drugs have not changed since 1994.

<sup>&</sup>lt;sup>4</sup> In the years 1997 through 1999, Baxter Medication Delivery had two different pricing levels: one for dealers, who distributed medical/surgical supplies and drugs, and another for wholesalers, who distributed only drugs. The WACs published during this period represent the highest of the WAC or Dealer Acquisition Costs (DAC) in a given year from 1997 to 1999.

#### C. Sales Data

The sales data provided below and in the accompanying materials are broken down by sales made to outpatient and inpatient settings based on customer codes assigned separately by Medication Delivery and Anesthesia & Critical Care, and market classifications used by BioScience.<sup>5</sup> As noted above, Baxter does not conduct business with PBMs, therefore, there is no sales data available for that customer category.

## D. Medicaid Rebate Data

In addition to the data requested by plaintiffs, Baxter has provided Medicaid rebate information, where applicable, to further bolster that certain drugs are sold primarily to providers for administration in inpatient settings. The administration of these drugs primarily in inpatient settings is shown by the relatively low volume of units reimbursed through Medicaid, as compared to the total number of units sold for each drug during the relevant time periods in question. Baxter contends that Medicaid outpatient utilization is an accurate reflection of Medicare outpatient utilization.

# III. Baxter's Drugs That Should Not Be In the AWP MDL

The drugs listed below are grouped under the Baxter division that manufactures them. Baxter either sold *de minimus* amounts of these drugs to providers for administration in the outpatient setting or did not sell them at all. Tab M contains a complete list of these drugs. Tab N is the list of drugs that would remain in the litigation.

# A. Drugs Produced by Baxter Medication Delivery:

# 1. Aggrastat

Appendix A to the AMCC incorrectly lists three formulations of Aggrastat as Baxter's drugs.<sup>6</sup> Baxter has never owned the 00006 labeler code. (see Tab A - Redbook pages, reflecting that Merck owns labeler code 00006). Instead, Baxter manufacturers Aggrastat for Merck. Baxter neither sells directly nor is involved in the pricing

<sup>&</sup>lt;sup>5</sup> A list of inpatient and outpatient codes, or market classifications, for each of Baxter divisions can be found in Tabs P (Medication Delivery), Q (Anesthesia & Critical Care), and R (BioScience).

<sup>&</sup>lt;sup>6</sup> The three formulations are: (1) Aggrastat Inj. 12.5/50 tirofiban HCl, NDC 00006-3713-25; (2) Aggrastat Inj. 12.5/50 tirofiban HCl, NDC 00006-3713-50; and (3) Aggrastat Inj.25 mg/500 tirofiban HCl in sodium chloride, NDC 00006-3739-55.

decisions concerning Aggrastat. Accordingly, Aggrastat should be deleted from Appendix A of the AMCC as to Baxter.

#### 2. Claforan

Claforan is typically administered in the inpatient setting to treat serious diseases and infections such as: (1) lower respiratory tract infections, including pneumonia caused by streptococcus pneumoniae and other streptococci; (2) genitourinary infections (urinary tract infections); (3) gynecologic infections, including pelvic inflammatory disease, endometritis and pelvic cellulites; (4) bacterremia/septicemia; (5) skin and skin structure infections; (6) intra-abdominal infections, including peritonitis; (7) bone and/or joint infections; and (8) central nervous system infections such as meningitis and ventriculitis.

Baxter manufactures a premixed Claforan injection as a frozen, iso-osmotic, sterile, nonpyrogenic solution, in two formulations:

Drug	NDC
1 g cefotaxime (free acid equivalent)	00039-0037-05
2 g cefotaxime (free acid equivalent)	00039-0038-05

From 1997 to 1999, more than 99% of Baxter's total sales of Claforan were to hospitals for inpatient administration and for which reimbursement is not based upon AWP. See Tab B-1. During this three year period, Baxter sold approximately \$110,000 annually of Claforan to providers for administration in the outpatient setting.<sup>7</sup>

For the reasons set forth above, the costs to pursue Claforan will far outweigh any potential recovery. Claforan should not be pursued in the AWP MDL.

<sup>&</sup>lt;sup>7</sup> Claforan is frozen and requires special freezers and shipping. As a result of these unique storage and handling requirements, it is only sold direct to customers and not through wholesalers. Thus, there is no WAC pricing for Claforan. For purposes of calculating a so-called "spread" for the less than 1% of Claforan sales potentially reimbursed based upon AWP, Baxter has provided the AWPs for Claforan. <u>See</u> Tab C. Given the low "spread" between ASPs and AWPs for Claforan, it is clear that any so-called "spread" between ASPs and WACs, had it existed, would have been reasonable.

## 3. Gentamicin

Isotonic Gentamicin Sulfate Injection is indicated in the treatment of serious infections including the treatment of bacterial neonatal sepsis; bacterial septicemia, and serious bacterial infections of the central nervous system (meningtitis), urinary tract, respiratory tract, gastrointestinal tract (including peritonitis), skin, bone, and soft tissue, as well as burns. It also has been used effectively in combination with carbenicillin for the treatment of life-threatening infections caused by Pseudomonas aeruginosa. These indications are treated primarily in the outpatient setting.

Baxter manufactures Gentamicin in eight formulations, varying only in strength of dosage and package quantity, all of which appear in Appendix A:

Drug	NDC
Isotonic Gentamicin Sulfate Inj. 100 mg/100 mL	00338-0505-48
Isotonic Gentamicin Sulfate Inj. 100 mg/50 mL	00338-0511-41
Isotonic Gentamicin Sulfate Inj. 120 mg/100 mL	00338-0507-48
Isotonic Gentamicin Sulfate Inj. 40 mg/50 mL	00338-0503-41
Isotonic Gentamicin Sulfate Inj. 60 mg/50 mL	00338-0507-41
Isotonic Gentamicin Sulfate Inj. 60 mg/100 mL	00338-0501-48
Isotonic Gentamicin Sulfate Inj. 80 mg/50 mL	00338-0509-41
Isotonic Gentamicin Sulfate Inj. 100 mL	00338-0503-48

As shown in Tab B-1, from 1997 to 1999 Baxter sold between 97% and 99% of the total sales for the above formulations to hospitals that administer the drug in an inpatient setting and are not reimbursed on the basis of AWP.

The relatively low volume of Gentamicin reimbursed through Medicaid further demonstrates that it is administered primarily in the inpatient setting. For example, of the 189,284 eaches / units sold from 1997 through 1999 of the first formulation of Gentamicin listed above (Sulfate Inj. 100 mg/100 ml, NDC 00338-0505-48), only 137 eaches / units, or .024%, were reimbursed through Medicaid. See Tab F. As shown in Tab F, from 1997 through 1999 the low number of eaches / units reimbursed through Medicaid for the other Gentamicin formulations fall well below 1% of the total eaches / units sold. Because the low level of outpatient usage of Gentamicin, plaintiffs should not pursue this drug in the MDL.

#### 4. Gentran

Appendix A to the AMCC identifies three variations of Gentran: Gentran 40, Gentran 75, and Gentran/Travasol. Each variation is addressed separately below:

#### a. Gentran 40

Gentran 40 is indicated in the inpatient setting for adjunctive use in the treatment of shock or impending shock caused by hemorrhage, burns, surgery, or other trauma. It also is indicated for use as a priming fluid, either as sole prime or as an additive, in pump oxygenators during extracorporeal circulation. Gentran 40 also is used in prophylaxis therapy against venous thrombosis and pulmonary embolism in patients undergoing procedures known to be associated with a high incidence of thromboembolic complication, such as hip surgery.

Appendix A to the AMCC lists four formulations of Gentran 40. Three of the four formulations appear to be invalid codes for which Baxter has not been able to locate sales or pricing information: (1) 10% Gentran 40 in D5W, (NDC 0038-0271-03); (2) Gentran 40 in saline, (NDC 0038-0269-03); and (3) 10% Gentran 40 in .9% sod. chl. (NDC 0038-0270-03).8 Accordingly, these three formulations should be deleted from Appendix A.

<sup>&</sup>lt;sup>8</sup> There are many reasons that could explain why these NDC codes could be invalid. For instance, they could be FDA-approved NDC codes that were never launched, or were launched but subsequently recalled but immediately terminated, or were launched and terminated prior to 1990. They also could be NDC codes that were

With respect to the only formulation of Gentran 40 listed in Appendix A for which Baxter has been able to validate – 10% Gentran 40 and 5% Dextrose, (NDC 0038-0272-03) – Baxter reported no sales.

#### b. Gentran 75

Appendix A to the AMCC correctly lists two formulations for Gentran 75. For one of the formulations, 6% Gentran 75 in saline, (NDC 0038-0263-03), the NDC appears to be an invalid code for which Baxter has not been able to locate sales or pricing information. Similarly, on the second formulation that is listed in Appendix A to the AMCC - 6% Gentran 75 in .9% sod. chl., (NDC 0038-0265-03), although the code appears in some of Baxter's internal records, Baxter has not been able to locate sales or pricing information. Thus, both formulations of Gentran 75 should be deleted from Appendix A.

## c. Gentran/Travasol

Appendix A to the AMCC correctly identifies one formulation for this drug: 10% Gentran Trav. Inj. in invert sugar, (NDC 0038-0267-03). The NDC, however, also appears to be an invalid code for which Baxter has not located any records showing sales or pricing information. Accordingly, the formulation should be deleted from Appendix A.

## 5. Heparin Lock

Heparin Lock is administered in inpatient hospital settings to maintain patency of an indwelling venipuncture device designed for intermittent injection, infusion therapy or blood sampling. It may be used following initial placement of the device in the vein, after each injection of a medication or after withdrawal of blood for laboratory tests.

Appendix A to the AMCC correctly identifies nine formulations for this drug:

erroneously cited in Appendix A to the AMCC, or were entered incorrectly by Baxter and as a result now appear by error in internal company records. As a result, Baxter has not been able to locate sales and pricing information for those NDC codes. A complete list of all NDC codes cited in Appendix A that appear to be invalid is found in Tab O.

Drug	NDC
100 U/ml Heparin Lock Inj.	00338-8112-69
100 U/ml Heparin Lock Inj.	00338-8212-69
100 U/ml Heparin Lock Inj.	00338-8213-70
100 U/ml Heparin Lock Inj.	00338-8113-70
100 U/ml Heparin Lock flush	00338-8206-69
solution, 3mL	
100U/ml Heparin flush, 3mL	00338-8209-69
100 U/ml Heparin Lock flush	00338-8210-70
solution, 5 mL	
10 U/ml Heparin Lock flush	00338-8106-69
solution, 3 mL	
10 U/ml Heparin Lock flush	00338-8110-70
solution, 5 mL	

With respect to the first four formulations listed above, the NDCs appear to be invalid codes for which Baxter has not been able to locate sales and pricing information. Accordingly, they should be deleted from Appendix A. <u>See</u> Tab O.

With respect to the last five formulations, there is no sales or pricing information to report from 1997 to 1999 because Baxter began selling these formulations in 2000. From 2000 to 2002, however, between 50% and 84% of Baxter's total sales for those five formulations were to inpatient settings. See Tab B-2. Although Heparin sales to outpatient settings for two of the formulations were close to 50%, the total sales for most of the formulations were relatively small during the entire three-year period: four of the five formulations reported total outpatient sales below \$200,000, and the remaining formulation reported total outpatient sales of \$823,410:

Drug	<b>Total Sales</b>	Outpatient Sales /
	(2000-2002)	Percentage of Total Sales
100 U/ml Heparin Lock	\$294,344.52	\$61,513.46/ 20.90%
flush solution, 3ml,		
(NDC 00338-8206-69)		
100 U/ml Heparin flush,	\$255,193.46	\$128,078.65/ 50.19%
3ml,		
(NDC 00338-8209-69)		

100 U/ml Heparin Lock	\$494,636.59	\$181,918.88 / 36.78%
flush solution, 5 ml,		
(NDC 00338-8110-70)		
10 U/ml Heparin Lock flush	\$200,976.9	\$33,011.17 / 16.43%
solution, 3 ml,		
(NDC 00338-8106-69)		·
10 U/ml Heparin Lock flush	\$1,670,372.37	\$823,410.66 / 49.30%
solution, 5 ml,		
(NDC 00338-8210-70)		

Given the low total sales for this drug, the costs of pursuing claims regarding these drugs far exceeds any potential recovery. Accordingly, plaintiffs should not pursue this drug in the MDL.

#### 6. Osmitrol

Osmitrol Injection (Mannitol Injection, USP) is used primarily in the inpatient setting for the promotion of diuresis, in the prevention and/or treatment of (1) the oliguric phase of acute renal failure before irreversible renal failure becomes established; (2) the reduction of intracranial pressure and treatment of cerebral edema by reducing brain mass; (3) the reduction of elevated intraocular pressure when the pressure cannot be lowered by other means, and (4) to promote urinary excretion of toxic substances.

Appendix A to the AMCC lists a total of 13 NDCs for this drug:

Drug	NDC
10% Osmitrol Inj.	00338-0345-03
10% Osmitrol Inj.	00338-0345-04
10% Osmitrol Inj.	00338-0354-04
15% Osmitrol Inj.	00338-0347-01
15% Osmitrol Inj.	00338-0347-03
20% Osmitrol Inj.	00338-0349-02
20% Osmitrol Inj.	00338-0349-03
5% Osmitrol Inj.	00338-0343-04
10% Osmitrol Inj.	00338-0353-03
15% Osmitrol Inj.	00338-0355-03
20% Osmitrol Inj.	00338-0357-02

5% Osmitrol Inj.	00338-0351-04
20% Osmitrol Inj.	00338-0357-03

In addition to the 13 formulations listed in Appendix A, Baxter has located one additional NDC for Osmitrol:

10% Osmitrol Injection, 1000 mL, NDC 00338-0353-04

With respect to the first 11 NDCs listed above, they appear to be invalid codes for which Baxter has not been able to locate sales and pricing information. Accordingly, they should be deleted from Appendix A to the AMCC. <u>See</u> Tab O.

Of the remaining three formulations for Osmitrol, 20% Osmitrol Injection, 500 mL, NDC 00338-0357-03 reported all sales from 1997 to 1999 to inpatient settings. See Tab B-1. For the other two NDCs, over 87% and 98% of the total sales from 1997 to 1999 were to inpatient settings:

Drug	Total Sales	Inpatient Sales /	Outpatient Sales /
		Percentage of Total	Percentage of Total
		Sales	Sales
5% Osmitrol Injection,	\$151,209.45	\$131,548.12 / 87%	\$19,661.33 / 13%
1000 mL,			
(NDC 00338-0351-04)			
10% Osmitrol Injection,	\$285,026.87	\$281,234.87 / 98.67%	\$3,792.00 / 1.33%
1000 mL,			
(NDC 00338-0353-04)			

<u>See</u> Tab B-1. Outpatient sales for these two formulations amounted to \$23,453.33 during the three-year period, or les than \$8,000 per year. <u>Id</u>.

The relatively low volume of these formulations reimbursed through Medicaid further demonstrates that these two NDCs for Osmitrol are administered primarily in the inpatient setting. For example, from 1997 to 1999, none of the eaches / units sold for 10% Osmitrol Injection, 1000 mL, NDC 00338-0353-04 were reimbursed through Medicaid. See Tab F. Similarly, of the 20,848 units sold of 1000 mL, 5% Osmitrol Injection, NDC 00338-0351-04, .00010% of eaches / units were reimbursed through Medicaid. Id. The minimal outpatient sales and low level of Medicaid outpatient usage for Osmitrol demonstrates that plaintiffs should not pursue this drug in the MDL.

#### 7. Travasol

Travasol is manufactured in several different formulations for different reasons. When sold as 5.5%, 8.5%, and 10% Travasol, the drug typically is used in inpatient settings as an adjunct in offsetting nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns. In its 3.5% formulation, however, Travasol is used to replace protein losses which occur in relation to an intercurrent phenomenon which is known or suspected to produce a protein loss condition for a short or moderate period of time.

Of the 34 formulations listed in Appendix A, the following three NDCs appear to be invalid codes for which Baxter has not been able to locate sales and pricing information:

Drug	NDC
Travasol	00338-0651-98
Travasol	00338-0653-98
8.5% Travasol w/electrolytes, 1000 mL	00338-0789-96

Accordingly, they should be deleted from Appendix A. See Tab O.

Of the remaining 31 NDCs listed in Appendix A, 18 of them appear to be valid codes, but do not have a corresponding Baxter catalog code. Although these NDCs could have been listed as FDA-approved NDC numbers, Baxter has not been able to locate sales or pricing information for them:

Drug	NDC
5.5% Travasol w/electrolytes, 500 ml,	00338-0457-03
5.5% Travasol w/electrolytes, 1000 ml	00338-0457-04
8.5% Travasol w/electrolytes, 1000 mL	00338-0459-04
5.5% Travasol w/electrolytes, 2000 mL	00338-0457-06
8.5% Travasol w/electrolytes, 2000 mL	00338-0459-06
5.5% Travasol w/o electrolyte, 500 mL	00338-0623-03
5.5% Travasol w/o electrolyte, 1000 mL	00338-0623-04
5.5% Travasol w/o electrolyte, 2000 mL	00338-0623-06
8.5% Travasol w/o electrolytes, 500 mL	00338-0625-03

3.5% Travasol M w/electrolyte 45, 500 ml	00338-0627-03	
3.5% Travasol M w/electrolyte 45, 1000 mL	00338-0627-04	
10% Travasol w/o electrolytes, 250 mL	00338-0629-02	
10% Travasol w/o electrolytes, 1000 mL	00338-0629-04	
10% Travasol w/o electrolytes, 2000 mL	00338-0629-06	
5.5% Travasol	00338-0785-98	
8.5% Travasol w/o electrolytes, 1000 mL	00338-0787-98	
8.5% Travasol w/electrolytes, 1000 mL	00338-0789-98	
5.5% Travasol w/o elec. & 50% dextrose,	00338-0829-04	
1000 mL		

Accordingly, there are no sales or pricing data to report on these NDCs, and they also should be deleted from Appendix A.

In addition, there are two Travasol NDCs for which Baxter had no outpatient sales:

Drug	NDC
8.5% Travasol w/o electrolytes, 1000 mL	00338-0625-04
8.5% Travasol w/o electrolytes, 2000 mL	00338-0625-06

<u>See</u> Tab B-2. Since these two formulations do not appear to have been purchased by any provider and, therefore, did not involve the payment of a copay, they also should be deleted from Appendix A.

Tabs B-1 and B-2 provide sales and pricing data for the remaining 11 Travasol NDCs listed in Appendix A to the AMCC. In addition to those 11 NDCs, Tab B-1 also contains data for 15 additional formulations of Travasol that were not included in Appendix A. As shown in Tab B-1, most of the total sales for most formulations of Travasol have been to inpatient settings. For instance, from 1997 to 1999, the following 18 formulations for Travasol reported inpatient sales of more than 90% from 1997 to 1999:

Drug	Percentage of Inpatient Sales
5.5% Travasol (Amino Acid) Inj,	95.19%
(NDC 00338-0458-03)	

94.66%
98.59%
94.83%
90.89%
90.36%
92.58%
96.98%
99.76%
99.45 %
90.02%
94.56%
94.75%
97.64%
99.83%
94.15%

8.5% Travasol w/ elec. and 20 %	91.30%
Dextrose,	
(NDC 00338-0853-04)	
8.5% Travasol w/ elec. and 50 %	97.06%
Dextrose,	
(NDC 00338-0859-04)	

<sup>\*\*\*</sup> Baxter's records show that from 1997 to 2003 these NDCs were not utilized under the Medicaid Rebate Program, <u>see Tab D</u>, which further demonstrates that these formulations are administered primarily in the inpatient setting.

The fact that four additional Travasol formulations reported 70% to 85% of total sales to providers in the inpatient setting, further demonstrates that Travasol is administered primarily in the inpatient setting:

Drug	Percentage of Inpatient Sales
8.5% Travasol w/o elec., 1000 mL,	82.96%
(NDC 0338-0626-04)	
3.5% Travasol w/ elec., 500 mL,	76.58%
(NDC 0338-0628-03)	
10% Travasol Inj. w/o elec., 500	84.59%
mL,	
(NDC 00338-0644-03)	
10% Travasol (Amino Acid) Inj.,	70.23%
(NDC 00338-0644-04)	

From 1997 through 1999, only one formulation of Travasol reported sales to outpatient patient settings at slightly more than 35% -- Travasol w/Lytes & 20 % DE, NDC 00338-0460-04 (36.09%). However, the total outpatient sales from 1997 through 1999 for this formulation of Travasol amounted to only \$184,069.87, or \$61,356 annually. See Tab B-1.

With respect to two other NDCs, Baxter began selling those formulations in 2000:

Drug	NDC
8.5% Travasol w/electrolytes, 500 mL	00338-0459-03
10% Travasol w/o electrolytes, 500 mL	00338-0629-03

As shown in Tab B-2, the sales for these NDCs were to inpatient settings and were nominal. With respect to the first formulation – NDC 00338-0459-03, 100% of total sales were to inpatient settings, and those sales amounted to only \$257.77 during 2000-2002. Similarly, the total sales for the second formulation listed above – NDC 00338-0629-03 – amounted to only \$1,013.68 from 2000 to 2002, and all of those sales were made to providers in inpatient settings.

Thus, of the 34 Travasol NDCs listed in Appendix A, only one formulation for Travasol, NDC 00338-0644-06, reported total outpatient sales of over \$1.4 million from 1997 to 1999. Outpatient sales for this formulation, however, amounted to only 17.29% of the total sales during the three-year period. Although the volume of sales for this NDC are significantly higher than the volume of sales for all other Travasol NDCs, close to 83% of its sales were primarily to providers in inpatient settings where reimbursement is not based on AWP. If plaintiffs, however, choose to pursue discovery on this one NDC, they should not pursue all other Travasol NDCs listed in Appendix A because, as noted above, their sales volume was low and they primarily were sold to providers in inpatient settings.

#### 8. Vancocin

Vancocin is typically used in inpatient hospital settings for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins, and for infections caused by Vancocin-susceptible organisms that are resistant to other antimicrobial drugs. Its effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin and skin structure infections.

Baxter produces Vancocin in two formulations: (1) Vancocin, 500 mg/100-ml (NDC 00338-3551-48); and (2) Vancocin, 1g/200 ml (NDC 00338-3552-48). As shown in Tab B-1, the overwhelming majority of Vancocin sales have been to the inpatient hospital settings – approximately 98% for the first formulation, and 90% for the second formulation. Sales to outpatient facilities are minimal, with about \$31,027.26 in outpatient sales for the first formulation, and \$2,174,614 for the second formulation from 1997 through 1999. The minimal outpatient sales for Vancocin demonstrate that plaintiffs should not pursue this drug in the MDL.

# B. Drugs Produced by Baxter Anesthesia & Critical Care:

## 1. Lorazepam

As an initial matter, Baxter did not own or sell Ativan injection during 1997 through 1999; rather, Baxter has been selling Lorazepam, the generic version of Ativan, since October 1998 after it purchased labeler code 10019 from Ohmeda.

Ativan/Lorazepam injection is indicated for the treatment of status epilepticus and as a pre-anesthetic medication for adult patients, producing sedation (sleepiness or drowsiness), relief of anxiety, and a decreased ability to recall events related to the day of surgery. It is most useful in those patients who are anxious about their surgical procedure and who would prefer to have diminished recall of the events of the day of surgery.

Appendix A to the AMCC identifies six formulations of Lorazepam injections purportedly manufactured by Baxter. This is incorrect. Of the six formulations, two appear to be invalid NDC codes for which Baxter has not been able to locate sales or pricing information: (1) 4 mg/mL, 1mL in 2 mL size syringe, NDC 10019-0103-46; and (2) 4 mg/mL, 10 ml vial, NDC 10019-0103-47. Thus, they should be deleted from Appendix A. See Tab O.

Baxter did not own or sell the remaining four formulations identified in the AMCC prior to 1998:

Drug	NDC
Lorazepam, 2 mg/ml, 1 ml vial	10019-0102-01
Lorazepam, 2 mg/ml, 10 ml vial	10019-0102-10
Lorazepam, 4 mg/ml, 1 ml vial	10019-0103-01
Lorazepam, 4 mg/mL, 10 mL SDV	10019-0103-10

As shown in Tab G, plaintiffs should not pursue the above four formulations of Lorazepam because over 99% of their total sales have been to providers in inpatient settings. In fact, from 1998 to 2000, Baxter sold only \$133,824, or less than \$45,000 annually, to providers for administration in the outpatient setting.

Baxter currently manufactures four formulations of Ativan injections, all of which were launched in 2004, after the filing of the MCC and thus are not subject to discovery.9

In summary, the foregoing demonstrates that plaintiffs should not pursue the formulations of Lorazepam cited in Appendix A to the AMCC.

#### 2. Brevibloc

Brevibloc, another drug administered primarily in the inpatient setting, is indicated for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter perioperative, postoperative, or other emergent circumstances where short term control of ventricular rate with a short-acting agent is desirable. Brevibloc also is indicated in noncompensatory sinus tachycardia where, in the physician's judgment, the rapid heart rate requires specific intervention. Brevibloc is not intended for use in chronic settings where transfer to another agent is anticipated. Brevibloc also is indicated for the treatment of tachycardia and hypertension that occur during induction and tracheal intubation, during surgery, on emergence from anesthesia, and in the postoperative period, when in the physician's judgment such specific intervention is considered indicated.

Baxter acquired Brevibloc in April 1998 in connection with its purchase of Pharmaceutical Products Inc., a pharmacy division of Ohmeda. Baxter currently sells Brevibloc in eight formulations. Four of the eight formulations of Brevibloc are not listed in Appendix A to the AMCC because Baxter began selling them after Plaintiffs filed the MCC:

 $<sup>^9</sup>$  The four new formulations Baxter launched in 2004 are: (1) 2mg per mL, NDC 60977-112-01, 25 x 1 mL vial; (2) 2mg per mL, NDC 60977-112-02, 10 x 10 mL vial; (3) 4mg per mL, NDC 60977-113-01, 25 x 1 mL vial; and (4) 4mg per mL, NDC 60977-113-02, 10 x 10 mL vial.

Drug	NDC	Launch Date
Brevibloc Double Strength Premixed Injection 2,000 mg/100 mL (20mg/ml) in 100 ml ready-to-use bags	10019-0075-87	May 27, 2003
Brevibloc Injection 100 mg/10 mL (10mg/ml) in 10 ml ready-to-use vials	10019-0115-01	July 1, 2003
Brevibloc Double Strength Injection 100 mg/5 mL (20mg/ml) in 5 ml ready-to- use vials	10019-0085-01	October 28, 2003
Novaplus Brevibloc 100mg Isotonic Inj., 10mg/mL	10019-0126-01	June 27, 2003

Accordingly, these formulations are not part of the MDL.

Of the four formulations of Brevibloc listed in Appendix A, Baxter began to sell two of them in 2001 and 2002:

Drug	NDC	Launch Date
Brevibloc, 2500 mg, 250 ml premix bag	10019-0055-61	March 14, 2001
Brevibloc Injection 100 mg/10 ml (10mg/ml) in 10 ml ready-to-use vials	10019-0015-01	April 25, 2002

As shown in Tab G, over 99% of the total sales for the above two formulations were to providers for administration in inpatient settings. See Tab G. In fact, total outpatient sales for both formulations amounted to only \$36,000. Id. In addition, the so-called "spreads" for both formulations were less than 10%. See Tab I.

With respect to the last two formulations of Brevibloc -- NDC 10019-0025-18 and NDC 10019-0015-71 - more than 99% of Baxter's total sales were to inpatient settings. See Tab G. Their so-called "spread" (250mg/ml) also were small, fluctuating between 6% to 12% during the same three-year period. See Tab I.

Given the low outpatient sales and the so-called "spreads" for all of the Brevibloc formulations, it is clear that the costs of pursuing Brevibloc will be higher than any potential recovery. Accordingly, plaintiffs should not pursue Brevibloc in the MDL.

# 3. Cisplatin

Cisplatin is typically administered in the inpatient setting for the treatment of metastatic testicular tumors and metastatic ovarian tumors in patients who have already received appropriate surgical and/or radiotherapeutic procedures. It also is used in the treatment of advanced bladder cancer in patients who are no longer amenable to local treatments such as surgery and/or radiotherapy.

Baxter began selling two formulations of Cisplatin in June 2000.

Drug	NDC
Cisplatin, 50 mg (1 mg/ml, 50 ml) vial	10019-0910-01
Cisplatin, 100 mg (1 mg/ml, 100 ml) vial	10019-0910-02

Less than 5% of the total sales for these two formulations were to outpatient settings. For instance, the total sales to outpatient settings for the first formulation of Cisplatin listed above, NDC 10019-0910-01, amounted to only \$20,703 from 2000 through 2002, less than 1% of the total sales. See Tab G. Similarly, Baxter sold only \$138,170 of the second formulation of Cisplatin - NDC 10019-0910-02 – to outpatient settings during the same three-year period. Those sales amounted to only 3.11% of the total sales. Id.

Because the costs to pursue Cisplatin will far outweigh any potential recovery, plaintiffs should not be pursue Cisplatin in the AWP MDL.

#### 4. Doxorubicin hcl

Doxorubicin hel is typically administered in inpatient settings to produce regression in disseminated neoplastic conditions such as acute lymphoblastic leukemia, acute myeloblastic leukemia, Wilms' tumor, neuroblastomas, soft tissue and bone sarcomas, breast carcinoma, ovarian carcinoma, transitional cell bladder carcinoma, thyroid carcinoma, gastric carcinoma, Hodgkin's disease, malignant lymphoma and bronchogenic carcinoma in which the small cell histologic type is the most responsive compared to other cell types.

Baxter began selling two formulations of Doxorubicin hcl in February 2001:

Drug	NDC
DOXORUBICIN INJ, 10 mg Powder, 10 mL	10019-0920-01
DOXORUBICIN INJ, 50 mg Powder, 50 mL	10019-0921-02

Plaintiffs should not pursue Doxorubicin in the AWP MDL because the total outpatient sales for this drug also are low and the costs of pursuing discovery will far exceed any potential recovery. For instance, from 2000 to 2002 Baxter sold only \$972 in outpatient sales of the first formulation of Doxorubicin – NDC 10019-0920-01. See Tab G. Similarly, from 2000 through 2002 Baxter sold only \$5,992 per year of the second formulation of Doxorubicin - NDC 10019-0921-02, or only 3.19% of the total sales during the three-year period. Id. Given the low total outpatient sales of Doxorubicin, plaintiffs should not be pursue Doxorubicin in the AWP MDL.

# C. Drugs Produced by Baxter BioScience:

#### 1. Bebulin VH

Bebulin Factor IX Complex is generally used to prevent and control hemorrhagic episodes in patients with Hemophilia B. Baxter manufactures one formulation of Bebulin: PDS, IV (vapor heated), 1 iu, ea, NDC 64193-0244-02. Although more than 60% of Bebulin's total sales have been made to outpatient settings, from 1998 to 2000, those sales amounted to only \$3.1 million dollars, or approximately one million dollars annually. See Tab J.

The relatively low volume of outpatient sales for Bebulin demonstrates that the costs of pursuing this drug in the MDL will outweigh any potential recovery.

## 2. Buminate

Buminate is typically used in inpatient settings to regain fluid volume. It is indicated for Hypovolemia, major burns and infections, major surgery, adult respiratory distress syndrome (ARDS), pulmonary edema, prior to and after cardiopulmonary bypass surgery, and to bind and remove toxic bilirubin in newborns with hemolytic disease.

Baxter manufactures five formulations of Buminate. As shown in Tab J, from 1997 to 1999, over 93% of the total sales of Buminate were to inpatient settings, where reimbursement is not based on AWP:

Drug	NDC	Percentage of Inpatient Sales
Buminate, 25%, 20 mL	00944-0490-01	98%
Buminate, 50 mL	00944-0490-02	94%
Buminate, 100mL	00944-0490-03	93%
Buminate, SOL, IV, 5%, 250 mL	00944-0491-01	95%
Buminate, 500 mL	00944-0491-02	95%

Further demonstrating that Buminate is administered primarily in the inpatient setting is the relatively low volume of the drug being reimbursed through Medicaid. As shown in Tab L, for example, from 1997 to 1999, 1% or less of the Buminate formulations were reimbursed through Medicaid.

Based on the low level of outpatient usage for Buminate, plaintiffs should not pursue this drug in the MDL.

# 3. Iveegam and Iveegam EN

Iveegam and Iveegam EN are indicated for replacement therapy in patients with primary immunodeficiency and treatment of Kawasaki syndrome. Baxter began selling Iveegam, 5gm, ea, NDC 54129-0233-50, in 1998 after acquiring Immuno. In

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August 1999, Baxter replaced Iveegam with Iveegam EN, 5gm, ea, NDC 64193-0250-50. 
<sup>10</sup> Tab J provides sales data for both Iveegam and Iveegam EN.

As shown in Tab J, from 1999 to 2001, over 94% of the sales of Iveegam EN have been to providers for administration in inpatient settings. In fact, outpatient sales during this three-year period have been less than one million annually. In addition, the low volume of eaches / units reimbursed for this drug through Medicaid further confirms that Iveegam EN is primarily used in inpatient settings. As shown in Tab L, from 2000 to 2002, of the total 757,945 eaches / units of Iveegam EN that were sold, only 2,248 were reimbursed through Medicaid, which amounted to less than one percent of the total eaches / units sold.

With respect to Iveegam, Tab J shows that from 1998 to 2000, about 55% of the total sales for Iveegam were to inpatient settings. However, the amount of sales to outpatient settings were relatively small, amounting to approximately \$500,000 annually.

Because the sales of Iveegam and Iveegam to providers administering the therapy in the outpatient setting are so low, plaintiffs should not pursue these therapies.

# IV. Conclusion

As demonstrated above, certain Baxter drugs should not be pursued by the plaintiffs in the AWP MDL. Tab N is the list of drugs that Baxter contends should be properly be subject to discovery.

After reviewing these materials, please contact me at your earliest convenience concerning plaintiffs' decisions regarding pursuing the drugs discussed herein.

//my

Andrés Colón

Counsel to Baxter Healthcare Corporation

 $<sup>^{10}</sup>$  Although Baxter stopped producing Iveegam in 1999, a limited number of sales for the drug were reported in 2000 and 2001.